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15 OCT 2002

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PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

# 6

In re the application of: M. Hanna et al.

Atty Docket No.: 0112.00

Examiner: Unassigned

Application No. 10/030,392

Group Art Unit: Unknown

Filed: January 2, 2002

October 3, 2002

Title: METHOD OF PARTICLE  
FORMATIONRECEIVED  
DEC 09 2002  
TC 1700

## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on 11 OCT 02

Signed: Minna CotterINFORMATION DISCLOSURE STATEMENTUNDER 37 CFR §1.56, §1.97 and §1.98

Commissioner for Patents  
Washington, DC 20231

Dear Sir:

The references listed in the attached Form PTO/SB/08A,B may be material to examination of the above-identified patent application. Applicants submit these references in compliance with their duty of disclosure pursuant to 37 CFR §§1.56, 1.97, and 1.98. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that these references indeed constitute prior art.

Copies of the references are enclosed, as required under 37 CFR §§1.98.

This Information Disclosure Statement is being timely filed under 37 CFR §§1.97 and is being filed:



within three months of the filing date of a national application; within three months of the date of entry of the national stage as set forth in section 1.491 in an international

Attorney Docket No. 0112.00

application; or before the mailing date of a first Office action on the merits (whichever event occurs last);

- ☐ more than three months from the filing date of an application and after the mailing date of a first Office action on the merits, but before the mailing date of either a final action under section 1.113 or a notice of allowance under section 1.311 (whichever occurs first), and is accompanied by:

- ☐ the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under §1.97(c) (\$180.00); or
- ☐ one of the following statements as specified in 37 CFR 1.97(e) that:
- ☐ each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- ☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in section 1.56(c) more than three months prior to the filing of the information disclosure statement; or

- ☐ after the mailing date of either a final action under section 1.113 or a notice of allowance under section 1.311, but on or before the payment of the issue fee, and is accompanied by each of:

- ☐ the following petition:
- Applicant hereby requests consideration of the accompanying information disclosure statement;
- ☐ the petition fee set forth in 37 CFR 1.17(i) (\$130.00); and
- ☐ one of the following statements as specified in 37 CFR 1.97(e) that:
- ☐ each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
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office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in section 1.56(c) more than three months prior to the filing of the information disclosure statement.

☐ Each item of information contained within this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement. Accordingly, this Information Disclosure Statement does not constitute a failure on the part of the Applicant to engage in reasonable efforts to conclude prosecution of the application as set forth in 37 CFR 1.704 "Reduction of period of adjustment of patent term."

☐ Attached is Check No. \_ in the amount of \$0.

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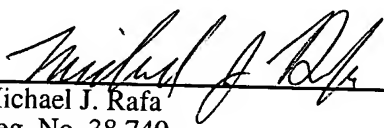
☒ If it is determined that any additional fees are due, the Commissioner is hereby authorized to charge such fees to Deposit Account 50-0348.

Respectfully submitted,

INHALE THERAPEUTIC SYSTEMS, INC.

Dated: 10/17/02

By:

  
Michael J. Rafa  
Reg. No. 38,740

San Carlos, CA 94070  
(650) 631-3100



PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

of

6

**Complete if Known**

Application Number	10/030,392
Filing Date	01/02/2002
First Named Inventor	M. Hanna et al.
Art Unit	
Examiner Name	Unassigned
Attorney Docket Number	0112.00

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US-4,328,107	05/04/1982	Wright	
	AB	US-4,361,285	11/30/1982	Koppehele et al.	
	AC	US-4,582,731	04/15/1986	Smith	
	AD	US-4,702,799	10/27/1987	Tuot	
	AE	US-4,737,384	04/12/1988	Murthy et al.	
	AF	US-4,919,853	04/24/1990	Alvarez et al.	
	AG	US-4,923,720	05/08/1990	Lee et al.	
	AH	US-4,970,093	11/13/1990	Sievers et al.	
	AI	US-4,977,785	12/18/1990	Willoughby et al.	
	AJ	US-5,009,367	04/23/1991	Nielsen	
	AK	US-5,043,280	08/27/1991	Fischer et al.	
	AL	US-5,106,659	04/21/1992	Hastings et al.	
	AM	US-5,221,731	06/22/1993	Weymans et al.	
	AN	US-5,229,486	07/20/1993	Paul et al.	
	AO	US-5,437,798	08/01/1995	LaRoche et al.	
	AP	US-5,548,004	08/20/1996	Mandel et al.	
	AQ	US-5,554,382	09/10/1996	Castor	
	AR	US-5,639,441	06/17/1997	Sievers et al.	
	AS	US-5,707,634	01/13/1998	Schmitt	
	AT	US-5,708,039	01/13/1998	Daly et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	AX	DE 4041563	06/25/1992	Schwarz Pharma AG		
	AY	DE 1078283	03/24/1960	F. Aktiengesellschaft		
	AZ	EP 0322687	05/05/1993	W. Fischer		
	BA	EP 0542314	05/19/1993	P. Debenedetti		
	BB	JP 1-176437	07/12/1989	T. Tauchi		
	BC	JP 5-57166	03/09/1993	K. Kitagawa		
	BD	WO 90/11139	10/04/1990	K. Nielsen		
	BE	WO 90/03782	04/19/1990	W. Schmitt		
	CP	GB 2322326	08/26/1998	Bradford Particle		
	CO	WO 95/21688	08/17/1995	W. Eckhard et al.		

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Control Number: Substitution for form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/030.392
				Filing Date	01/02/2002
				First Named Inventor	M. Hanna et al.
				Art Unit	
				Examiner Name	Unassigned
				Attorney Docket Number	0112.00
Sheet	2	of	6		

[illegible][illegible]

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<b>Substitute for form 1449B/PTO</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>  (use as many sheets as necessary) Sheet <u>3</u> of <u>6</u>		<b>Complete if Known</b>	
		Application Number	10/030.392
		Filing Date	01/02/2002
		First Named Inventor	M. Hanna et al.
		Group Art Unit	
		Examiner Name	Unassigned
		Attorney Docket Number	0112.00

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
BF		DEBENEDETTI ET AL., "Application of Supercritical Fluids for the Production of Sustained Delivery Devices," J. Cont. Rel. No. 24, p. 27-44 (1993).
BG		DIXON ET AL., "Polymeric Materials Formed by Precipitation with a Compressed Fluid Antisolvent," AIChE J. Vol. 39 (No. 1), p. 127-139 (1993).
BH		TOM ET AL., "Applications of Supercritical Fluids in the Controlled Release of Drugs," ACS Symposium Series, Supercritical Fluid Engineering Science Fundamentals and Applications, Chpt. 19, p. 238-257 (1993).
BI		LARSON ET AL., "Evaluation of Supercritical Fluid Extraction in the Pharmaceutical Industry," Biotech. Progress, Vol. 2 (No. 2), p. 73-82 (1986).
BJ		Ullmans Encyclopedia of Industrial Chemistry, Vol. B2, Fifth Ed., title page, copyright page, and p. 7-21 and 7-22 (1988).
BK		TOM ET AL., "Particle Formation with Supercritical Fluids - A Review," J. Aerosol Sci., 1st Ed. Vol. 22 (No. 5), p. 555-584 (1981).
BL		DEBENEDETTI ET AL., "Rapid Expansion of Supercritical Solutions (RESS): Fundamentals and Applications," Fluid Phase Equilibria, Vol. 82, p. 311-321 (1993).
BM		GALLAGHER ET AL., "Gas AntiSolvent Recrystallization: New Process to Recrystallize Compounds Insoluble in Supercritical Fluids," ACS Symp. Ser No. 406, p. 334-354 (1989).
BN		LAHIERE ET AL., "Mass-Transfer Efficiencies of Column Contactors in Supercritical Extraction Service," Ind. Eng. Chem. Res. No. 26, p. 2086-2092 (1987).
BO		STAHL ET AL., "Dense Gas Extraction on a Laboratory Scale: A Survey of Some Recent Results," Fluid Phase Equilibria, No. 10, p. 269-278 (1983).
BP		DILL ET AL., "Denatured States of Proteins," Annu. Rev. Biochem, No. 60, p. 795-825 (1991).

Examiner Signature		Date Considered	
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		Application Number	10/030.392
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	of	First Named Inventor	M. Hanna et al.
	6	Group Art Unit	
		Examiner Name	Unassigned
		Attorney Docket Number	0112.00

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	CB	RANDOLPH ET AL., "Sub-Micrometer-Sized Biodegradable Particles of Poly (L-Lactic Acid) via the Gas Antisolvent Spray Precipitation Process." Biotechnol. Prog. Vol. 9, No. 4, p. 429-435 (1993).
	CC	DEBENEDETTI ET AL., "Supercritical Fluids : A New Medium for the Formation of Particles of Biomedical Interest," Proceed. Intern. Symp. Control Rel. Bioact. Mater., 20, p. 141-142 (1993).
	CD	DONSI ET AL., "Micronization by Means of Supercritical Fluids: Possibility of Application to Pharmaceutical Field," Pharm. ACTA HELV. 66, Nr. 5-6, p. 170-173 (1991).
	CE	CYGNAROWICZ ET AL., "Design and Control of a Process to Extract B-Carotene with Supercritical Carbon Dioxide." Biotechnol. Prog. Vol. 6, p. 82-91 (1990).
	CF	CHEN ET AL., "Supercritical Antisolvent Fractionation of Polyethylene Simulated with Multistage Algorithm and SAFTEquation of State: Staging Leads to High Selectivity Enhancements for Light Fractions," Ind. Eng. Chem. Res., Vol. 33, p. 306-310 (1994).
	CG	LOTH ET AL., "Properties and Dissolution of Drugs Micronized by Crystallization from Supercritical Gases," International J. of Pharmaceuticals, Vol. 32, p. 265-267 (1986).
	CH	BODMEIER ET AL., "Polymeric Microspheres Prepared by Spraying Into Compressed Carbon Dioxide," Pharmaceutical Research, Vol. 12, No. 8, p. 1211-1217 (1995).
	CI	TOM ET AL., "Formation of Bioerodible Polymeric Microspheres and Microparticles by Rapid Expansion of Supercritical Solutions," Biotechnol. Prog., Vol. 7, p. 403-411 (1991).
	CJ	SANCHEZ ET AL., "Development of Biodegradable Microspheres and Nanospheres for the Controlled Release of Cyclosporin A," International J. of Pharmaceutics, Vol. 99, p. 263-273 (1993).
	CK	JULIENNE ET AL., "Preparation of Poly (D, L-Lactide/Glycolide) Nanoparticles of Controlled Particle Size Distribution: Application of Experimental Designs," Drug Development and Industrial Pharmacy, Vol. 18, No. 10, p. 1063-1077 (1992).
	CL	PHILLIPS ET AL., "Rapid Expansion from Supercritical Solutions: Application to Pharmaceutical Processes," International J. of Pharmaceutics, Vol. 94, p. 1-10 (1993).

Examiner Signature	Date Considered
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		Filing Date	01/02/2002
		First Named Inventor	M. Hanna et al.
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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS		
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		CHANG ET AL., "Precipitation of Microsize Organic Particles from Supercritical CM Fluids," AIChE Journal, Vol. 35, No. 11, p. 1876-1882 (November 1989).
		MATSON ET AL., "Rapid Expansion of Supercritical Fluid Solutions: Solute Formation of Powders, Thin Films and Fibers." Ind. Eng. Chem Res., Vol. 26, p. 2298-2306 (1987).
		STENGERS ET AL., "Carbon Dioxide at its Critical State," Chemical & Engineering News, June 10, 1968.

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